NEUROSTIMULATING LEAD

Background of the Invention

I. Field of the Invention: This invention relates generally to implantable leads for conducting electrical signals to and/or from a stimulating pulse generator, and more particularly to neurostimulating leads having electrodes and so sized such that they are adapted to be percutaneously inserted into the epidural space and advanced beyond an intervertebral foramen to the dorsal or ventral nerve roots and into the sheath containing nerve fibers for stimulation of selected peripheral nerves in addressing chronic pain resulting from neurogenic, neuropathic or neuroceptive nerve conditions.

II. Discussion of the Prior Art: Conventional neural stimulation therapies rely on electrode catheters for stimulating various regions of the spinal cord that correspond to each physiologic region of the body. Spinal cord stimulation, however, has limited effectiveness for certain pain conditions primarily due to limited accessibility to targeted nerve routes. In many cases where spinal cord stimulation is inadequate, peripheral nerves must be stimulated to provide pain relief. However, with existing technology, this can only be accomplished with a surgical implant, which results in scarring and significant patient discomfort. Therefore, physicians need greater specificity and broadened accessibility to perform a broader array of nerve stimulation, using less invasive methods to improve treatment outcome.

A variety of medical electrode catheters are available today for the diagnosis and treatment of various disorders of the cardiovascular and neurological systems. These electrode catheters can be used to sense electrical activity within the body and to deliver different forms of energy to stimulate, ablate, cauterize or pace. The core electrode technology common to all of these catheter designs is the application of one or more metallic bands on a catheter body. Example of medical catheters using

metallic banded electrodes include permanent and temporary cardiac pacing leads, electrophysiologic (EP) catheters, electrocautery probes and spinal stimulation catheters. The use of pre-formed metallic band electrodes manufactured from nobel metals, such as gold or platinum and various other conductive alloys has found wide-spread application despite their functional design and performance limitations. Metallic band electrodes possess several distinct performance problems. When placed on flexible catheter materials, they add significant stiffness that greatly interferes with the steerability of such catheters. As such, prior art catheters having band electrodes are often restricted to applications where steerability and selective placement are not required. In addition, when DC or RF energy is applied to metallic band electrodes, a thermal field is generated which can interfere with energy delivery, increased power consumption and, in blood environments, create potentially life-threatening blood clots. Finally, the manufacture of catheters utilizing metallic band electrodes is quite labor-intensive, resulting in high manufacturing costs.

Placement of leads for both external and implantable RF stimulating devices is quite simple for spinal cord stimulation. Here, a Tuohy needle is inserted into the spinal epidural space and the leads are placed adjacent to the targeted nerves addressing a specific painful region of the body. Relatively high power must be applied when directly stimulating the spinal nerves compared to that required when peripheral nerve stimulation is involved. While this is not a problem when the spinal leads are used with an external stimulator for which battery replacement is relatively easy. It is a major limitation of totally implantable systems in that high power consumption necessarily shortens the time between surgeries for battery replacement. Procedurally, nerve stimulation therapy becomes more challenging when peripheral nerves or segmental regions of the body are targeted. Due to the

fact that many regions of the body cannot be effectively stimulated via the spinal cord, the only alternative in many cases is to surgically implant electrodes. Therefore, a significant need exists for therapeutic access to nerve networks without surgical intervention.

The neurostimulating leads of the present invention eliminate many of the problems encountered with conventional, band-electrode leads. The method employed in fabricating leads of the present invention afford the ability to fabricate highly flexible electrodes on extremely small diameter catheter lead bodies while, if desired, still providing a central lumen permitting such catheters to be advanced over a guidewire until the electrodes thereon on disposed adjacent target tissue.

It is accordingly a principal object of the present invention to provide an improved method for fabricating electrical stimulating leads of reduced diameter and carrying a plurality of longitudinally spaced electrodes at the distal end thereof, each of the electrodes being individually connected to a connector at the proximal end thereof by conductors that are embedded within the wall of the lead body and insulated from one another.

Another object of the invention is to provide a method of fabricating such a lead while still maintaining a high degree of steerability thereof.

A further object of the invention is to provide an improved neurostimulating lead having a plurality of longitudinally-spaced, multi-layer, thin film electrodes proximate its distal end, where the electrodes are connected by spiral wound wires embedded in the wall of the lead body and where the lead body can, if desired, retain a central lumen through which a guidewire may pass.

Yet another object of the invention is to provide a construction of micro-lead catheters in very small diameters that maximizes inner lumen space for over-the-wire delivery, infusion of fluids, multi-electrode lead wires and steering systems. The resulting leads provide

enhanced sensitivity to low level signals, providing improved output clarity and lower energy requirements when delivering stimulating currents to selected nerve tissue.

SUMMARY OF THE INVENTION

The foregoing objects and advantages of the invention are realized by devising a neurostimulating lead having an elongated, thin, flexible tubular body member of a predetermined length and with annular wall defining an internal lumen that either extends from the proximal end to the distal end of that body member or over a sheet segment at the distal end of the body member. A plurality of spiral wound conductors are embedded within the wall of the tubular body member and are electrically insulated from one another. They extend from the distal end to the proximal end of the body member. A plurality of multi-layer thin film metal electrodes are deposited on the outer surface of the annular wall of the body member at discrete longitudinally-spaced locations in a zone proximate the distal end of the body member. To establish an electrical connection between the thin film electrodes and the buried spiral wound conductors, a plurality of tunnels are formed radially through the body member from the outer surface of the annular wall reaching the buried conductors. Laser etching is a preferred way of forming such tunnels. An electroplating operation is then employed to create conductive links that extend through the tunnels from the buried conductors to the wall surface on which the thin film electrodes are later deposited. The lead further includes at least one connector at its proximal end. The connector includes a plurality of contacts that are electrically joined to the plurality of conductors. The connector is adapted to connect the lead to either an implanted or an external neurostimulator.

Utilizing the manufacturing method described herein, it has been possible to produce neurostimulating leads having an outer diameter of only 0.026 inch (2 Fr.) and with an internal lumen diameter of about 0.012 in.,

allowing the catheter to be passed over a 0.010 guidewire. The thin film electrodes are typically less than about 250 microns in thickness and, as such, do not detract from the flexibility of the resulting catheter and its ability to be readily steered through the epidural space and out through a selected intervertebral foramen beyond the dorsal or ventral root fibers and into the sheath surrounding the target peripheral nerves to be stimulated by using a guidewire and an over-the-wire catheter delivery.

DESCRIPTION OF THE DRAWINGS

The foregoing features, objects and advantages of the invention will become apparent to those skilled in the art from the following detailed description of a preferred embodiment, especially when considered in conjunction with the accompanying drawings in which like numerals in the several views refer to corresponding parts.

Figure 1 is a partial perspective view of a neurostimulating lead constructed in accordance with the present invention;

Figure 2 is an enlarged cross-sectional view taken along the line 2-2 in Figure 1;

Figure 3 is a greatly enlarged schematic illustration of a portion of the lead of Figure 1 showing a thin film ring electrode deposited on the catheter as being transparent to show underlaying spiral wound conductors and the location of connecting links;

Figure 4 is a cross-sectional view taken along the line 4-4 in Figure 1;

Figure 5 is a cross-sectional view taken along the line 5-5 in Figure 1;

Figure 6 is a segmented view of a distal end portion of a lead constructed in accordance with the present invention having longitudinally overlapping electrode segments;

Figure 7 is a segmented view showing a distal end portion of a lead with a different longitudinally overlapping electrode segment arrangement; and

Figure 8 is a process flow chart illustrating the steps involved in fabricating the neurostimulating lead of Figure 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figure 1, there is indicated generally by numeral 10 a neurostimulating lead constructed in accordance with the present invention. It is seen to include an elongated, flexible, plastic tubular member 12 having a proximal end 14 and a distal end 16 and a lumen 18 (Figure 2) extending therebetween. The tubular body member 12 is preferably formed from a suitable medical grade polymer with polyurethane being preferred. The outside diameter of the tubular member 12 may be in a range of about 0.020 to 0.030 in. with 0.026 in. (2 Fr.) being preferred. The inside diameter of the tubular member, i.e., the lumen 18 may be about 0.012 in. when the outside diameter is 2 Fr.

Referring again to the cross-sectional view of Figure 2, it can be seen that there is embedded within the wall of the tubular member 12 a plurality of electrical conductors 20, 22, 24 and 26 which preferably have a rectangular cross-section measuring approximately 0.004 in. in width and 0.002 in. in thickness. The enlarged schematic drawing of Figure 3 shows that these relatively flat conductors are spiral wound and they extend from the proximal end 14 to the distal end 16 of the tubular catheter body 12. The spiral winding is such that each of the conductors is physically spaced from an adjacent neighbor and in that they are buried or submerged within the polymer comprising the tubular body 12, they are electrically insulated from one another. Without limitation, the pitch of the spiral windings may be such that the turns are at an angle of about 45° to the longitudinal axis of the tubular body member, it being understood that the pitch is directly dependent on the number of electrodes and therefor the number of conductors traversing the wall of the tubular body member.

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Sputtered or vapor-deposited on a distal end portion of the catheter are a plurality of longitudinally spaced electrodes 28, 30, 32 and 34. These electrodes are formed using the method described in co-pending application of Eugene Champeau, serial no. 09/176,009, filed October 20, 1998, and entitled "Catheter With Thin Film Electrodes and Method for Making Same", which is assigned to the assignee of the present invention. The teachings of that application are hereby incorporated by reference. Each of the electrodes thus preferably comprises a plurality of superposed metallic layers, each exhibiting a nanocrystaline plate-like structure. As is explained in the Champeau application cited, the innermost metal film layer may typically be 5 microns or less in thickness and may be titanium, chromium, nickel or aluminum. By using a known ion-bombardment technique, the metal comprising the base layer is made to aggressively adhere to the outer surface of the polyurethane lead body 12. Next, a layer of metal, such as platinum or palladium may be vacuum-deposited onto the base layer to a thickness in a range between, for example, 500 angstroms and 50 microns to serve as an oxygen diffusion barrier layer. Following that, a second intermediate conduction layer of gold, platinum, silver or copper may be vacuum-deposited onto the exterior of the preceding layer in an ion-bombardment process and built up to a thickness in a range between a minimum of about 2 microns and a maximum of 250 microns. The outermost layer is selected for its bio-compatibility properties and high conductivity with gold, platinum or platinum iridium being preferred. The thickness of the outer layer may range from between about 500 angstroms and 50 microns.

With no limitation intended, each of the deposited electrodes 28, 30, 32 and 34 may be about 3 mm. in length and may be separated from its adjacent electrode by a gap distance of about 4 mm.

To establish an electrical connection between the embedded spiral-wound conductors and the individual thin film electrodes, before the thin film electrodes are vapor-deposited or otherwise formed on the surface of the tubular body member, a laser beam is used to burn through the elastomeric wall of the tubular body member to form radially extending tunnels down to the conductors. Once the tunnels are so formed, an electroplating process is used to create a metal link through the tunnel extending from the embedded conductor to the exterior surface of the tubular body member. Now, when the thin film electrodes are deposited onto the wall surface, the electroplated links provide a conductive path between the electrodes and their respective individual conductors.

Figure 3 schematically illustrates this arrangement. Here, four conductors labeled **A** through **D** are embedded within the wall of the tubular body member 12 and a plurality of tunnels are represented on the drawing by the small circles 36. These tunnels penetrate through the wall 12 to contact only conductor **A**. Once the tunnels are formed, the lead may be placed in an electroplating bath with a DC voltage being applied to the conductor **A** at its proximal end. The plating bath will preferably contain free ions of a metal selected from the group including gold, silver, platinum, titanium, and platinum iridium. The application of the DC voltage will cause the metal ions to migrate through the tunnels, building up a conductive link therein in the same fashion that plated-through-holes on printed circuit boards are commonly fabricated.

Once the tunnels 36 have been metalized, a thin film electrode, as at 28, may be vapor-deposited through a suitable mask onto the wall surface of the tubular body member 12. The dimensions of the thin film electrodes may be established such that they are made to span two turns of a given conductor. In Figure 3, the thin film electrode 28 is shown as spanning two turns of the conductor **A**. This allows that a sufficient number of conductive links in the

form of tunnels 36 to be made to join the electrode to its associated embedded conductor to insure a low ohmic coupling between the two. However, it is also possible to use a shorter electrode that spans only a single turn. In Figure 3, the portion of the conductor, **A**, traversing the far side of the catheter is shown in dashed lines. In the view of the Figure 4, the electroplated conductive links joining the conductors 20-26 to the thin film electrodes 32 are identified by numeral 38.

Figures 6 and 7, respectively show a preferred electrode arrangement wherein plural, longitudinally-spaced electrode structures, each comprising a bipolar pair of longitudinally overlapping conductive electrodes, where one is adapted to be connected to a positive voltage, the other to a negative voltage and either can be turned on or off by a physician at the time of lead implant. In Figure 6, there are shown two pairs of electrodes, the first pair labeled **A** and **B** and the second pair **C** and **D**. Of course, more than two such pairs can be provided proximate the distal end portion of the lead. Each electrode segment, **A**, **B**, **C**, **D**, can be selectively connected to a positive or a negative polarity voltage or can be off, i.e., connected to neither. Each segment has a separate conductor connected to it leading back to a connector at the proximal end of the lead. In Figure 6, the lead is masked such that when the thin film electrodes are vacuum deposited thereon, the segments **A** and **B** overlap one another over one-half their length. In the arrangement of Figure 7, each electrode segment encircles the lead body over an arc slightly less than 180° so as to remain separate.

Using these arrangements, **A** may be designated to be positive when turned on and **B** may be negative when turned on. Likewise, **C** could be designated to be negative when turned on and **D** positive when turned on. If **A** and **B** are both turned on, the stimulating current would flow through nerve tissue bridging segments **A** and **B**. However, if **A** and **C** are both turned on with **B** and **D** both off, the stimulating

current path is significantly longer, going from electrode segment **A** to electrode segment **C**.

To mate the lead 10 with a stimulating pulse generator, an in-line connector 40 is formed on the proximal end 14 of the lead body 12. It comprises a relatively inflexible, molded body 42 that is concentrically disposed over a portion of the lead 12 at its proximal end that supports a plurality of conductive contact rings 44-50 that are longitudinally spaced from one another along the length of the body member 42. The conductive rings are electrically connected to the embedded conductors 20-26 in a fashion substantially similar to that used in connecting the conductors to the ring electrodes 28-34. That is, tunnels are formed through the lead body 12 and an electroplating process is used to create conductive links leading to vapor deposited or sputtered metallization on the exterior surface of the lead body. Now, the preformed rings 44-50 of a substantial radial thickness can be slipped onto the proximal end of the lead body and into electrical contact with the metallized patterns on the lead body surface.. Now, a suitable elastomer, such as silicone rubber or polyurethane, is injection molded over the rings to hold them in place. Any plastic material on the outer surfaces of the rings is removed to allow good ohmic contact with electrical contacts of the pulse generator.

The tubular connector body 42 also preferably has a central lumen allowing a guidewire to pass therethrough and through the lumen of the lead body 12 for over-the-wire placement of the lead. This same lumen can be used for fluid injection, drug delivery or other purposes known in the art. It is not essential to the invention that the lad body be tubular since a steerable tip may be provided on the distal end of the lead, obviating the need for a guidewire.

Having described the constructional features of the neurostimulating lead of the present invention,

consideration will next be given to the method or process for fabricating same. In this regard, reference is made to the block diagram process flow chart of Figure 6.

The first step in the process, reflected by box 52 is to use a conventional extruder to form the tubular body member from a suitable elastomeric material, preferably polyurethane. Knowing the number of electrodes and, therefore, the number of conductors needed to convey signals from and to those electrodes, a formula is applied to determine the O.D. of the tubing to be extruded so that when the conductors are embedded therein, the resulting subassembly will be of a specified O.D. desired, such as about 2 Fr.

The next step in the process is to spiral-wind and embed the conductors into the tubing wall and this is preferably accomplished using the method described and claimed in the Burnham Patent 4,764,324, the teachings of which are hereby incorporated by reference. In accordance with that method, the extruded tubular member is threaded over a cylindrical mandrel whose O.D. corresponds to a desired lumen size and then heating the catheter body member to the point where when the plurality of conductors are spirally wound under appropriate tension forces, the conductors will be submerged within the tubing wall. Subsequently, the outer surface of the catheter body member is smoothed by passing it through a heated dye to effectively remove any deformations created when the conductors are embedded within the catheter wall.

Once the tubular body member with the embedded conductors is completed as a subassembly, the mandrel will be removed and the catheter cut to a desired length. Next, the distal end portion of the lead body and a portion that is to become part of the connector at the proximal end are subjected to a laser etching process whereby tunnels are created that penetrate through the plastic down to the embedded conductors. Following that, the lead is placed in an electroplating bath to create the conductive links, as

at 38 and 48 in Figures 4 and 5, between the embedded conductor and the surface of the lead body and connector body.

Using the method set out in the aforereferenced Champeau patent application, multiple electrodes are vacuum-deposited onto the proximal and distal end portions of the lead, with suitable masking techniques being used to establish the respective lengths and shape configurations of the electrodes and the spaces therebetween. The vapor-deposited electrodes bond to the conductive links previously electrodeposited into the tunnels in the lead body so as to establish continuous electrical paths between the respective electrodes and corresponding ones of the embedded conductors.

Finally, the connector contacts 44-50 are affixed to the connector body 42 at the proximal end of the lead, such contacts also being joined to the embedded spiral-wound conductors by the previously electroplated links and the deposited film electrodes. The proximal end of the lead supporting the contact rings 44-50 is then inserted into a mold and plastic is injection molded onto the lead to provide support for the contact rings.

This invention has been described herein in considerable detail in order to comply with the patent statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and operating procedures, can be accomplished without departing from the scope of the invention itself.

What is claimed is:

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